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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/098,690	03/15/2002	Stephen Grimes	17118-058002/ 2837B	6943	
20985 FISH & RICHA	7590 02/05/2007 ARDSON PC		EXAMINER		
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MINNEAPOLI	15, MN 33440-1022		ART UNIT PAPER NUMBER 1723		
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SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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	Application No.	Applicant(s)	
	10/098,690	GRIMES ET AL.	`
Office Action Summary	Examiner	Art Unit	
	John Kim	1723	
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet	with the correspondence add	iress
A SHORTENED STATUTORY PERIOD FOR REPI WHICHEVER IS LONGER, FROM THE MAILING I - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the mailinearned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMU .136(a). In no event, however, may d will apply and will expire SIX (6) No te, cause the application to become	NICATION. y a reply be timely filed MONTHS from the mailing date of this core ABANDONED (35 U.S.C. § 133).	
Status			
1)⊠ Responsive to communication(s) filed on <u>01 l</u>	December 2006.		
2a) This action is FINAL . 2b) ⊠ Thi	is action is non-final.	-	
3) Since this application is in condition for allowa	ance except for formal m	atters, prosecution as to the	merits is
closed in accordance with the practice under	Ex parte Quayle, 1935 C	D. 11, 453 O.G. 213.	
Disposition of Claims			
4) Claim(s) 1,3-6 and 15-28 is/are pending in the 4a) Of the above claim(s) is/are withdra 5) Claim(s) is/are allowed. 6) Claim(s) 1,3-6 and 15-28 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/	awn from consideration.		
Application Papers			
9) ☐ The specification is objected to by the Examin 10) ☑ The drawing(s) filed on 15 March 2002 is/are: Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) ☐ The oath or declaration is objected to by the E	a) accepted or b) ⊠ of a drawing(s) be held in abegotion is required if the drawi	yance. See 37 CFR 1.85(a). ng(s) is objected to. See 37 CFI	R 1.121(d).
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureat* See the attached detailed Office action for a list	nts have been received. Its have been received in ority documents have been (PCT Rule 17.2(a)).	n Application No en received in this National S	Stage
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date 12/1/06.	Paper N	w Summary (PTO-413) lo(s)/Mail Date of Informal Patent Application (PTO-	-152)

- 1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/1/06 has been entered.
- 2. Claim 20 is objected to because of the following informalities: A period after "a)", "b)" and "c)" on lines 11, 13 and 14 respectively should be removed. Appropriate correction is required.
- 3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the electronic sensors and valve assemblies connected to a computer, a chromatographic device, an affinity and/or gel filtration column and a solid state peptide synthesis system must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 5. Claims 1, 3, 5-6, 16-17, 20, 21 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Jonsson (US Pat. No. 4,579,662).

Regarding claims 1, 16 and 20, Jonsson teaches a closed and sterile system comprising an filter device (10) having a membrane with a pore size of 0.2 micron i.e. ultrafiltration/concentration means, a reaction vessel (15) connected to the filter device (10), a backwash reservoir (25) connected to the filter device (10) and a pump and a valve (14) on a tube (13) interconnected between the filter device (10) and the reaction vessel (15) and a tube (22) interconnecting the filter device (10) and the backwash reservoir (25) (see figures 2-4; col. 1, line 66 – col. 2, line 6; col. 3, lines 28-36; col. 4, line 6 – col. 5, line 66; col. 7, line 64 – col. 8, line 47). Recitations of "A system for the continuous liquid phase modification and/or conjugation of proteins, purification and concentration thereof" in claim 1 and "A system for the continuous liquid phase modification and/or conjugation, purification and concentration of proteins" and

"the tubing is configured to allow: <u>a). a reaction solution ...</u> b). a reverse flow ... c). a retentate from the ultrafiltration..." in claim 20 are an intended use of the apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Regarding claims 3 and 21, Jonsson teaches a three way valve (75) selectively connected to the reaction vessel (15) and the filter device (10) and situated between the reaction vessel (15) and the filter device (10) and the backwash reservoir (25) (see figure 6; col. 8, lines 15-55).

Regarding claims 5 and 23, Jonsson teaches that the filter device (10) is connected to the permeate reservoir (19) (see figures 2-4; col. 4, lines 20-24).

Regarding claim 6, Jonsson teaches that the reaction vessel (15) is connected to the concentrated suspension vessel (21) (see figure 6; col. 6, lines 19-23).

Regarding claims 17 and 24, Jonsson teaches a control device, inherent computer, for automatic control of valves and flows responding to sensors (see col. 6, line 66 – col. 7, line 7; col. 9, lines 25-36).

6. Claims 1, 4-6 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Breslau et al (US Pat. No. 4,986,918).

Regarding claims 1, 16 and 20, Breslau et al teach a closed and sterile system comprising an ultrafiltration membrane module, a reaction vessel (T1) connected to the ultrafiltration membrane separation module, a backwash reservoir (T2) connected to the ultrafiltration membrane separation module and a pump (P) and valves (V1-V4) interconnected between the ultrafiltration membrane separation module and the reaction vessel (T1) and tubing (5, 7, 8, 9,

10) fluidly connecting the ultrafiltration membrane module, the reaction vessel (T1), a pump (P), valves (V1-V4) and the backwash reservoir (T2) (see figures 1-7; col. 4, line 10 – col. 6, line 68). Recitations of "A system for the continuous liquid phase modification and/or conjugation of proteins, purification and concentration thereof" in claim 1 and "A system for the continuous liquid phase modification and/or conjugation, purification and concentration of proteins" and "the tubing is configured to allow: a). a reaction solution ... b). a reverse flow ... c). a retentate from the ultrafiltration..." in claim 20 are an intended use of the apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Regarding claims 4 and 22, Breslau et al teach that the membranes used in ultrafiltration may be in spiral wound configuration (see col. 1, lines 43-45).

Regarding claims 5 and 23, Breslau et al teach that the ultrafiltration membrane separation module is connected to the permeate reservoir (T2) (see figures 3-7).

Regarding claim 6, the reaction vessel (T1) receives purified concentrated product from the ultrafiltration separation module (see figures 1-4).

7. Claims 1, 5-6, 16 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Malik et al (US Pat. No. 6,027,853).

Regarding claims 1 and 16, Malik et al teach a closed and sterile system comprising an ultrafiltration membrane module (10), a reaction vessel (22) connected to the ultrafiltration membrane module (10), a backwash tank (34) being fluidly connected to the ultrafiltration membrane module (10) and a pump (24) interconnected between the ultrafiltration membrane

module (10) and the reaction vessel (22) (see figures 1-2; col. 5, line 7 – col. 7, line 10). Recitations of "A system for the continuous liquid phase modification and/or conjugation of proteins, purification and concentration thereof" in claim 1 is an intended use of the apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Regarding claim 5, Malik et al teach that the permeate is collected in a permeate tank (32) (see figure 2; col. 6, lines 64-67).

Regarding claim 6, Malik et al teach that the reaction vessel (22) receives purified concentrated product from the ultrafiltration membrane module (10) (see figure 2; col. 6, lines 45-54).

Regarding claim 18, Malik et al teach a gel chromatographic device for evaluating retentate and permeate (see col. 8, lines 30-51).

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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- 9. Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malik et al as applied to claim 1 above, and further in view of Buckley et al (US Patent No. 5,342,863). Malik et al teach a closed and sterile system as described in above paragraph. Malik et al teach that the ultrafiltration membrane module is used to purify polymer resins (see col. 2, lines 17-28; col. 5, lines 8-64). Claims 4 and 17 essentially differs from the system of Malik et al in reciting a spiral diafiltration cartridge (claim 4) and a series of electronic sensors and valve assemblies connected to a computer (claim 17). Buckley et al teach a system comprising an ultrafiltration module including spiral-wound membrane cartridge and a series of automated control valves for controlling the flow of the process fluid including reverse flow wherein the ultrafiltration module is used to separate out polymer lattices from white water (see abstract; col. 7, lines 48-62; col. 8, lines 52-63; col. 10, lines 25-54). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the system of Malik et al to substitute known spiral-wound ultrafiltration membrane cartridge for ultrafiltration membrane module of Malik et al and include a series of electronic sensors and valve assemblies connected to a computer for automating control valves for controlling the flow of the process fluid including reverse flow as suggested by Buckley et al (see col. 10, lines 25-54).
- 10. Claims 20 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malik et al in view of Buckley et al. Malik et al teach a closed and sterile system as described in above paragraph. Malik et al further teaches that tubing (26, 28, 36) fluidly interconnecting the ultrafiltration membrane module (10), the reaction vessel (22), a pump (24) and the backwash

reservoir (34) (see figure 2; col. 6, line 42 – col. 7, line 10). Malik et al further teach that the ultrafiltration membrane module is used to purify polymer resins (see col. 2, lines 17-28; col. 5, lines 8-64). Claims 20, 22 and 24 essentially differ from the system of Malik et al in reciting a flow control unit comprising at least one valve (claim 20), spiral diafiltration cartridge (claim 22) and a series of electronic sensors and valve assemblies connected to a computer (claim 24). Buckley et al teach a system comprising an ultrafiltration module including spiral-wound membrane cartridge and a series of automated control valves for controlling the flow of the process fluid including reverse flow wherein the ultrafiltration module is used to separate out polymer lattices from white water (see abstract; col. 7, lines 48-62; col. 8, lines 52-63; col. 10, lines 25-54). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the system of Malik et al to substitute known spiral-wound ultrafiltration membrane cartridge for ultrafiltration membrane module of Malik et al and include a series of electronic sensors and valve assemblies connected to a computer for automating control valves for controlling the flow of the process fluid including reverse flow as suggested by Buckley et al (see col. 10, lines 25-54).

Regarding claim 23, Malik et al teach that the permeate from the outlet of the ultrafiltration membrane module is collected in a permeate tank (32) (see figure 2; col. 6, lines 64-67).

Regarding claims 25-26, Malik et al teach a gel permeation chromatographic device for evaluating retentate and permeate (see col. 8, lines 30-51).

11. Claims 1, 5-6, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brochure from AMICON re "Operating Principles of Ultrafiltration Systems" (hereinafter

referred to as Pub 750) in view of Moller (US Pat. No. 5,620,065). Pub 750 teaches a closed ultrafiltration system comprising an ultrafiltration membrane device, a reaction vessel connected to the ultrafiltration membrane device, and a pump and valve interconnected between the ultrafiltration membrane device and the reaction vessel (see figures 1-2; pages 1-2). Claims 1 and 20 essentially differs from the apparatus of Pub 750 in reciting a backwash reservoir being fluidly connected to the ultrafiltration means. Pub 750 recognizes that the ultrafiltration cartridges retain LPS pyrogens and pyrogens are removed by periodic flushing (see pages 3-4). Moller teaches a system comprising ultrafiltration membrane device (13) with a backwash tank (18) for backwashing fluid to the permeate side of membrane to remove contaminants from the membrane (see figure 1; col. 5, lines 64-65; col. 11, lines 21-58; col. 13, lines 13-48). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Pub 750 to include a backwash reservoir containing backwashing fluid connected to the ultrafiltration membrane device for effectively storing the backwash fluid to backflush the membrane as suggested by Moller.

Regarding claims 5 and 23, Pub 750 teaches that the ultrafiltration membrane device is connected to the permeate reservoir (see figures 1-2).

Regarding claim 6, Pub 750 teaches that reaction vessel containing process fluid receives concentrated product (see figures 1-2).

Claims 4 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pub 750 12. in view of Moller as applied to claims 1 and 20 above and further in view of AMICON Brochure re Spiral-Wound/Hollow Fiber System (hereinafter referred to as AMICON). Pub 750 in view of Moller teaches a closed ultrafiltration system as described in above paragraph. Pub 750 further

teaches a diafiltration cartridge (see page 2, figure 2). Claims 4 and 22 essentially differ from the system of Pub 750 in view of AMICON in reciting a spiral diafiltration cartridge. AMICON teaches an ultrafiltration system including a spiral wound diafiltration cartridge (see page 54, 25). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute a spiral diafiltration cartridge for the cartridge in the system of Pub 750 for its equivalent ultrafiltration capability.

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Claims 1, 3, 5-6, 15-16, 20-21, 23 and 28 are rejected under 35 U.S.C. 103(a) as being 13. unpatentable over Meier (US Pat. No. 5,262,053) in view of Moller. Meier teaches a system comprising an filter device (2) with ultrafiltration membrane, a reaction vessel (7) connected to the filter device (2), a backwash source (18) connected to the filter device (10) and a pump (9) and valve (V-4) interconnected between the filter device (2) and the reaction vessel (7) and tubing (8, 16, 18) fluidly interconnecting the filter device (10), the reaction vessel (7), the pump (9), a valve (V-4) and a line to a backwash source (18) (see figure 1; col. 5, line 61 – col. 7, line 18). Claims 1, 16 and 20 essentially differ from the apparatus of Meier in reciting a backwash reservoir. Meier teaches that backwash source is water or cleaning liquids which is directed to the permeate side of the membrane (see col. 6, lines 11-15; col. 7, lines 10-17). Moller teaches a system comprising ultrafiltration membrane device(13) with a backwash tank (18) for backwashing fluid to the permeate side of membrane to remove contaminants from the membrane (see figure 1; col. 5, lines 64-65; col. 11, lines 21-58; col. 13, lines 13-48). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Meier to include a backwash reservoir containing water or cleaning

liquids connected to the ultrafiltration membrane device (2) for effectively storing the backwash fluid to backflush the membrane in a closed and sterile system.

Regarding claims 3 and 21, Meier teaches a three way valve (17) selectively interconnected and situated between the reaction vessel (7) and the filter device (2) and the backwash source (18) (see figure 1; col. 6, lines 11-15; col. 6, line 56 - 17).

Regarding claims 5 and 23, Meier teaches that the filter device (2) is connected to the permeate reservoir (19) (see figure 1; col. 5, line 68 – col. 6, line 2).

Regarding claim 6, Meier teaches that the unfiltered medium e.g. protein is pumped from the reaction vessel (7) through the filter (2) and then return into the reaction vessel (7) (see col. 7, lines 37-39) in that the reaction vessel (7) is a receptacle of the purified concentrate product from the filter (2).

Regarding claims 15 and 28, Meier teaches that the reaction vessel (7) contains a tanning agent and/or protein and stabilizer i.e. reactant (see col. 2, line 3 -30; col. 6, lines 40-42).

14. Claims 4 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meier in view of Moller as applied to claims 1 and 20 above, and further in view of Breslau et al and AMICON. Meier in view of Moller teaches the ultrafiltration system as described in above paragraph. Meier teaches a microporous membrane in tube form (see col. 8, lines 64-67). Claims 4 and 22 essentially differ from the systems of Meier in view of Moller in reciting a spiral diafiltration cartridge as the ultrafiltration means. Breslau et al teach that membranes used in ultrafiltration may be of various configurations such as hollow fiber, flat sheet, spiral wound or tubular (see col. 1, lines 43-46). AMICON teaches a ultrafiltration system comprising an ultrafiltration membrane device of a spiral wound/hollow fiber diafiltration cartridge for efficient

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processing of macromolecular solutions or cell suspensions (see page 54, 16, 24). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute a spiral wound/hollow fiber diafiltration cartridge for tubular membrane of Meier for efficient processing of macromolecular solutions as in the solutions treated in Meier as suggested by AMICON and Breslau et al.

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- 15. Claims 19 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meier in view of Moller as applied to claims 1 and 20 above, and further in view of Chang et al (US Patent No. 5,380,495). Meier in view of Moller teaches the ultrafiltration system as described in above paragraph. Claims 19 and 27 essentially differ from the systems of Meier in view of Moller in reciting a solid state peptide synthesis system. Chang et al teach a solid state peptide synthesizer including solvent/reagent delivery and measuring system coupled to a reaction vessel (see abstract; col. 5, lines 33-51; RV in Figure 1). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the system of Meier in view of Moller to include a solid state peptide synthesis system to synthesize peptides to be purified in the system of Meier in view of Moller.
- 16. Applicant is advised that should claim 15 be found allowable, claim 28 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
- 17. Applicant's arguments with respect to claims 1, 3-6 and 15-28 have been considered but are moot in view of the new ground(s) of rejection.

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Applicants argue that Meier does not teach a closed system because the retentate is discarded. However, Meier also teaches that unfiltered medium is pumped in a known manner from the working tank (7) i.e. reaction vessel through the filter (2) and then returns into the working tank (7) showing a closed system (see col. 7, lines 34-50). Applicants also argue that Moller does not teach or suggest a closed system. However, the backwash tank (18) of Moller connected to a backwash source line (18) of Meier forms a closed system. Moller further teaches that a separate conduit for removing the backwash which permeates through the membranes may be incorporated into the system and such means can recycle the backwashed material to the backwash tank or remove it from the system (see col. 11, lines 38-45). Applicants argue that the system of Breslau et al is open system. However, Breslau et al is a closed system in terms of recycling capability of retentate and permeate in the system (see figures 1-7).

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- 18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 4,800,166 teaches an automated peptide synthesis system.
- 19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

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information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

John Kim

Primary Examiner
Art Unit 1723

JK 1/31/07